THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 57

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RICHARD S. HANSON, MICHAEL C. FLICKINGER, FREDERICK J. SCHENDEL and MICHAEL V. GUETTLER

Appeal No. 94-3255
Application 07/673,264[1]

HEARD: DECEMBER 10, 1998

Before CAROFF, GRON and ELLIS, **Administrative Patent Judges**.

ELLIS, **Administrative Patent Judge**.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claim 55. Claims 1 through 24, 37 through 39 and 49 have been withdrawn from consideration pursuant to 37 CFR § 1.142(b). Claims 25, 26 through 36, 40 through 48, 50

[1] Application for patent filed March 20, 1991. According to the appellants, this application is a continuation of Application 07/335,691, filed April 10, 1989, now abandoned.

through 54, 56 and 57 have been canceled.

Claim 55 reads as follows:

55. An amino acid producing auxotrophic bacterium of a biologically pure strain ribulose monophosphate pathway utilizing bacterium ***Bacillus*** MGA3, or biologically pure strain corresponding environmental isolate of ***Bacillus*** MGA3 having all of the identifying characteristics of ***Bacillus*** MGA3 or biologically pure strain stable morphological mutants of said ***Bacillus*** MGA3 or its corresponding environmental isolate, said auxotroph exhibiting sustained growth at 50EC in nutrient media comprising methanol as a source of carbon and energy and vitamin B_{12}, and excreting at least about 5 g/l of lysine, aspartic acid, phenylalanine, or tryptophan when growth on a media containing a nitrogen source.

Claim 55 stands rejected under (i) the second paragraph of 35 U.S.C. § 112 as failing to particularly point out and distinctly claim the subject matter which the appellants regard as the invention, and (ii) the first paragraph of § 112, as the claim is not supported by an enabling disclosure and an adequate written description.

The examiner does not rely on any references to support the rejections.

We have carefully considered the entire record which includes, ***inter alia***, the specification, the appellants' Brief, Reply Brief and Supplemental Reply Brief, as well as the examiner's Answer and Supplemental Answer. We affirm the

rejection under 35 U.S.C. § 112, second paragraph, and reverse the rejections under the § 112, first paragraph. While we are affirming under § 112, second paragraph, the reasons for which we do so differ somewhat from those of the examiner. Accordingly, we denominate our affirmance as a new ground of rejection under 37 CFR § 1.196(b).

Opinion

We note at the outset that the examiner has issued "two" § 112 rejections. The first, is a combination of a § 112, second paragraph, and a § 112, first paragraph, enablement rejection. The second, is a § 112, first paragraph, written description rejection based on the appellants' failure to deposit certain biological strains. With this in mind, we point out that it is well established that that claim analysis "should begin with the determination of whether the claims satisfy the requirements of the second paragraph," of 35 U.S.C. § 112. ***In re Moore***, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). In ***Moore*** the court stated:

> [I]t should be realized that when the first paragraph speaks of "the invention", it can only be referring to that invention which the applicant wishes to have protected by the patent

> grant, i.e., the *claimed* invention. For this reason the claims must be analyzed first in order to determine exactly what subject matter they

> encompass. The subject matter there set out must be presumed, in the absence to evidence to the contrary, to be that "which the applicant regards as his invention."
>
> This first inquiry therefore is merely to determine whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. It is here where the definiteness of the language employed must be analyzed--not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art [footnote and citation omitted].

Thus, before we can consider the § 112, first paragraph, enablement and written description issues, we must first determine whether claim 55 satisfies the requirements of § 112, second paragraph.

As a starting point, we find it helpful to delineate the four groups of bacteria encompassed by the claim. The concurring opinion interprets the claim as being directed exclusively to auxotrophic bacteria (Concur., p. 6, n.3), but we do not find that to be the case. Rather, we find that claim 55 is directed to:

> (1) An amino acid producing auxotrophic bacterium of a biologically pure strain ribulose-monophosphate-pathway utilizing ***Bacillus*** MGA3, wherein said auxotroph exhibits

> sustained growth at 50EC in a nutrient medium[2] comprising methanol as a source of carbon and energy and vitamin B_{12}, and excreting at least about 5 g/l of lysine, aspartic acid, phenylalanine, or tryptophan when grown on a medium containing a nitrogen source;
>
> (2) A biologically-pure strain corresponding environmental isolate of ***Bacillus*** MGA3 having all of the identifying characteristics of ***Bacillus*** MGA3;
>
> (3) Biologically-pure, stable morphological mutants of said ***Bacillus*** MGA3; and
>
> (4) A corresponding environmental isolate of a biologically-pure, stable, morphological mutant of said ***Bacillus*** MGA3.

In breaking up the claim in this manner, it becomes apparent that while it encompasses the strains disclosed in the specification; ***viz***., ***Bacillus*** MGA3, NOA2, and Gr; none are specifically claimed. In addition, by specifically delineating these categories, it is easier to analyze the claim, and to determine the merits of the examiner's rejections.

Turning first to the examiner's contention that the

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[2] We note that claim 55 is directed to "nutrient media" and "media containing a nitrogen source." It is not clear why the claim is directed to the plural form of this term. Perhaps, upon return of this application to the corps, the examiner should consider whether the use of the term "media" is vague and confusing under 35 U.S.C. § 112, second paragraph.

recitation in claim 55 of "an auxotrophic bacterium of... Bacillus MGA3,"[3] is vague and indefinite (and, presumably, fails to satisfy the requirements of the second paragraph of § 112), we find her argument: that it is not clear whether the appellants intend to claim "a mutant of ***Bacillus*** MGA3 or ***Bacillus*** MGA3 itself," to be unpersuasive. Answer, p. 5. Rather, we agree with the appellants that the plain meaning of the word "of" as being "obtained or derived from," indicates that the claim is directed to auxotrophic mutants derived from ***Bacillus*** MGA3.

As to the recitation of a "corresponding environmental isolate of ***Bacillus*** MGA3," (See Categories (2) and (4), above), we agree with the examiner that the phrase is vague and indefinite. However, we do not find that the examiner has considered this phrase in the context of the category(ies) wherein it appears. In our opinion, the examiner has focused too narrowly on only a portion of the claim both with respect to category 2 and category 4, above.

Concerning category 2, we find that, in its entirety, it

[3] See Category (1).

is directed to a "corresponding environmental isolate of ***Bacillus*** MGA3 having all of the identifying characteristics of ***Bacillus*** MGA3." Before one can begin to determine which bacteria are encompassed by "corresponding environmental isolates," it is necessary first to understand what the appellants intend by "having all the identifying characteristics of MGA3." Here, we part company with our colleague's analysis. According to the concurring opinion, the identifying characteristics of ***Bacillus*** MGA3 are listed in Table 1[4] on p. 8 of the specification. Concurring opinion, p. 7. We disagree. Rather, we direct attention to the title of the referenced table, "Characteristics of Type I Methylotrophic ***Bacillus***," which, on its face, indicates that it does not list all the "identifying characteristics of ***Bacillus*** MGA3." According to the specification, ***Bacillus*** MGA3 is a member of a genus of microorganisms which exhibit the characteristics listed in the table. Specification, p. 7.

[4] We note that the specification contains two tables labeled "Table 1." We direct attention to pp. 8 and 25. In the event of further prosecution of this application, the appellants should correct this error.

Thus, Table 1 (p. 8 of the specification), lists some, but not "all the identifying characteristics of ***Bacillus*** MGA3."

It is well established that "the analysis [of] claims which on first reading - in a vacuum, if you will - appear indefinite may upon a reading of the specification disclosure or prior art teachings become quite definite. It may be less obvious that this rule also applies in the reverse, making an otherwise definite claim take on an unreasonable degree of uncertainty." ***In re Moore***, 439 at 1235, n.2, 169 at 238, n.2. Thus, we look first to the specification to determine what the appellants intend by "having all the identifying characteristics of ***Bacillus*** MGA3." Here, we find that the specification states, ***inter alia***, that "[m]icroorganisms that utilize one-carbon compounds more than carbon dioxide (methylotrophs) are diverse and ubiquitous." Specification, p. 1. The specification further states that the "methylotrophic bacterium of a preferred embodiment of the present invention is a member of the genus ***Bacillus*** having the characteristics as set forth in

Table 1."[5] Specification, p. 7. The specification still further states that ***Bacillus*** strain MGA3 exhibited the characteristics indicated in Table 1 and was further characterized "by an aberrant form in which very large and pleomorphic cells were occasionally visible in smears of strain MGA3 cultures." Specification, para. bridging pp. 8-9. Finally, the specification describes numerous characterization tests of ***Bacillus*** MGA3 on pp. 21-26.

In considering these statements, we also note that the specification uses the term "having" and "exhibits" in referring to the methylotrophic bacteria of a preferred embodiment of the present invention and ***Bacillus*** MGA3, respectively. Specification, pp. 7-9. In our view, these terms are "open" in the sense that the bacteria described therein "have" or "exhibit" the cited characteristics, as well as additional characteristics. That is, methylotrophic ***Bacillus*** "have" the characteristics set forth in Table 1,

[5] Here, the specification refers to the Table 1 set forth on p. 8. Unless otherwise indicated, when the Table 1 is referred to, we intend the table on p. 8 of the specification.

however, the term "have" does not preclude their having additional characteristics. And, while ***Bacillus*** MGA3 exhibits an aberrant form in cultural smears, the term "exhibits" does not preclude the bacterium from having additional characteristics.

Thus, in reading the claim in light of the specification, we do not find that the indefiniteness issue is resolved. That is, in reading the specification, nowhere do we find a disclosure as to what constitutes "all the identifying characteristics of ***Bacillus*** MGA3." What are all the characteristics of ***Bacillus*** MGA3? Do the appellants intend the results of the characterization tests set forth on pp. 21-26 of the specification to describe "all the identifying characteristics

of ***Bacillus*** MGA3?" Do the appellants intend the list of characteristics set forth in Table 1 and the characteristic of having an occasional pleomorphic cell present in cell cultures, to be a description of all the identifying characteristics of ***Bacillus*** MGA3? If so, what is the

difference between ***Bacillus*** MGA3 and other methylotrophic ***Bacillus*** described in the prior art; e.g., the methylotrophic ***Bacillus*** described by Dijkhuizen?

As to the entire phrase "a corresponding environmental isolate having all the identifying characteristics of ***Bacillus*** MGA3," in Category 2, above, again, we turn to the specification to determine whether claim 55 "set[s] out and circumscribe[s] a particular area with a reasonable degree of particularity."
In re Moore, 439 F.2d at 1235, 169 USPQ at 238. To that end, we find that the specification describes the isolation of ***Bacillus*** MGA3 from the freshwater marsh soil. Specification, pp. 16-17. The specification further states that NOA2 was isolated from a separate source and exhibits identical characteristics as MGA3. Specification, p. 27.

The examiner has stated, and the appellants do not disagree, that by "corresponding environmental isolate," they do not intend ***Bacillus*** MGA3; otherwise, they would not have employed the term "corresponding" in the claim. The specification does not state that NOA2 is a "corresponding

environmental isolate... of ***Bacillus*** MGA3;" rather, it appears to indicate that NOA2 is identical to ***Bacillus*** MGA3.[6] Nowhere in the specification do we find a description of what constitutes an environmental isolate which "corresponds" to, and which "has all the identifying characteristics of," ***Bacillus*** MGA3. Do the appellants intend all Type I methylotrophic ***Bacillus***, isolated from the environment, as corresponding to ***Bacillus*** MGA3? All Type I methylotrophic bacteria? What characteristics distinguish a corresponding environmental isolate having all the characteristics of ***Bacillus*** MGA3 from ***Bacillus*** MGA3 itself?

As to the indefiniteness of a "corresponding environmental isolate of a biologically-pure, stable, morphological mutant of ***Bacillus*** MGA3" in Category 4 above, here, too, we find that the determination of the metes and bounds of this phrase must start with an analysis of the latter portion of the phrase; i.e., what do the appellants intend by a biologically-pure, stable morphological mutant of

[6] If ***Bacillus*** NOA2 and MGA3, are identical, we find the difference in nomenclature unclear.

Bacillus MGA3 (see Category 3).

According to the examiner, "the recitation of 'biologically pure strain stable morphological mutants' renders the claim indefinite, since it is unclear what is encompassed thereby." Answer, p. 6. In response, the appellants argue that "[t]he variety in bacterial shapes are known to those of skill in the art and ***Bacillus*** species are typically rod shaped. Bacteria having the other identifying characteristics of ***Bacillus*** MGA3 but differing in shape would be readily recognized by one of skill in the art as morphological mutants." Brief, para. bridging pp. 11-12. The appellants point to the disclosure of the isolation of strain Gr to support their position. ***Id***. We agree that strain Gr is one type of morphological mutant encompassed by claim 55, but the claim is not limited to that strain. Nor, contrary to the appellants' argument, is the claim limited to bacteria wherein the only difference between the mutant and ***Bacillus*** MGA3 is a difference in shape. That is, Category 3 is not directed to stable, morphological mutants having all of the identifying characteristics of

MGA3.[7] Rather, Category 3 encompasses ***Bacillus*** MGA3 which have changes in morphology, as well as other biological properties. Since the specification only describes one morphological mutant, the relevant inquiry, here, is: what morphological mutants, other than strain Gr, are encompassed by the claim? While we agree that the claim encompasses that which the appellants appear to argue; i.e., morphological mutants which arise within a culture of ***Bacillus*** MGA3, yet are identical to ***Bacillus*** MGA3 in every other respect, we find the claim vague and indefinite in that it is unclear what additional mutants of ***Bacillus*** MGA3 the appellants intend.

The concurring opinion concludes that claim 55 is indefinite because (i) it appears to be directed to a nutrient medium which does not contain biotin, (ii) it appears to be directed to a nutrient medium which includes carbon and energy sources other than methanol, such as glucose or mannitol, (iii) it is not clear what amounts of amino acid production the appellants intend, and (iv) it is not clear that the

[7] Note the discussion above, with respect to the indefiniteness of the phrase "having all the identifying characteristics of ***Bacillus*** MGA3."

claimed amount of amino acid production is possible in the claimed nutrient media, or any other media. We disagree. In addition, we find that the issues raised in (i) and (iv), above, involve enablement issues under 35 U.S.C. § 112, first paragraph, not indefiniteness.

As to our colleague's conclusion that the claim is indefinite for the reason set forth in subsection (i), we point out that claim 55 is “open” in that it is directed to a nutrient medium “comprising” the listed components. Thus, the claim does not exclude the presence of additional factors needed to sustain bacterial growth such as a phosphate, a sulfate, etc. While the claim does not recite biotin as an ingredient, the open claim language certainly encompasses its inclusion. Therefore, in our view, the issue is not one of indefiniteness since the claim does not mandate the presence of biotin but, rather, does the specification provide a disclosure which would have enabled one skilled in the art to “make and use” an auxotrophic mutant capable of excreting the claimed amino acids in a nutrient media which does not contain

biotin.[8] See enablement discussion under ***Other Issues***, below.

As to our colleague's conclusion that claim 55 is indefinite for the reason set forth in subsection (ii), we find it inconsistent with the conclusion concerning the presence of biotin in the nutrient medium. That is, on the one hand he finds that because it is not recited, claim 55 excludes biotin. Now, he concludes that because of the open language, the claim includes carbon and energy sources other than methanol. To that end, we agree that it does. However, in reading the claim in light of the specification, we find that it defines methylotrophs as microorganisms that utilize one-carbon compounds more reduced than carbon dioxide as their energy source. Specification, p. 1, lines 15-17. The specification discloses that facultative methylotrophs (which

[8] ***Cf. In re Mayhew***, 527 F.2d 1229, 1233, 188 USPQ 356, 358 (CCPA 1976)("Although appellant now strenuously argues that the cooling bath is optional, his specification not only fails to support this contention, but leads us, as it did the examiner and board, to believe that both it and its location are essential. We therefore conclude that claims which fail to recite the use of a cooling zone, specially located, are not supported by an enabling disclosure").

include, ***inter alia***, ***Bacillus***)- are microorganisms which can utilize methanol, methylamine or both as a source of carbon and energy.[9] Specification, p. 1, lines 29-37. The specification further discloses that a "preferred nutrient media for culturing the bacterium [sic, bacteria] of the present invention to produce amino acids includes a carbon and energy source, preferably methanol...." ***Id***., p. 3, lines 28-32. The specification does not describe any other compounds as carbon and energy sources for the claimed ***methylo***trophs (emphasis added). Thus, while the claim language is "open" to other carbon and energy sources, it appears to be open in a very limited sense, to the further inclusion of methylamines only.

As to our colleague's conclusion (subsection (iii) above) that the phrase "excreting at least about 5 g/l of lysine, aspartic acid, phenylalanine, or tryptophan," is indefinite, we disagree. In view of the use of the conjunctive "or," we

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[9] The specification also describes obligate methylotrophs as microorganisms which utilize methane as a source of carbon and energy. However, since all these microorganisms are said to be gram-negative, this group does not include the gram-positive microorganisms of the genus ***Bacillus***.

find that the claim is directed to auxotrophic mutants capable of excreting at least about 5 g/l lysine, 5 g/l aspartic acid, 5 g/l phenylalanine ***or*** 5 g/l tryptophan.

Finally, we do not agree with our colleague's conclusion that the claim is indefinite for the reason set forth in subsection (iv), above. In our view, the issue is not whether the claim is unclear as to what is the quantity of each of the amino acids that will satisfy the functional limitations specified therein but, rather, whether the specification disclosure would have enabled one skilled in the art to "make" auxotrophic mutants capable of excreting at least about 5 g/l lysine, 5 g/l aspartic acid, 5 g/l phenylalanine or 5 g/l tryptophan. See the enablement discussion, below.

Accordingly, we affirm the examiner's rejection under 35 U.S.C. § 112, second paragraph, but we denominate our affirmance as a new ground of rejection under 37 CFR § 1.196(b) in order to provide the appellants with a fair opportunity to respond. In view of our holding that claim 55 is indefinite, we are unable to determine whether it complies with the requirements of the first paragraph of § 112. Thus,

we reverse the examiner's rejections under this section of the statute and direct attention to the ***Other Issues*** section, ***infra***.

Other Issues

In the event of further prosecution of this application, there are several issues which should be considered by the examiner and the appellants.

I.

As discussed above, the enablement issues raised by the examiner cannot properly be explored until the record is clear as to just what the claimed invention is. ***Panduit Corp. v. Dennison Mfg. Co.***, 810 F.2d 1561, 1567, 1 USPQ2d 1593, 1597 (Fed. Cir. 1987); ***In re Moore***, ***supra***. To satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, the specification must teach one skilled in the art how to “make and use” the full scope of the claimed invention without undue experimentation. ***PPG Indus. v. Guardian Indus. Corp.***, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996); ***In re***

Wright, 999 F.2d 1557, 1561, 27 USPQ 1510, 1513 (Fed. Cir. 1993); ***In re Vaeck***; 947 F.2d 488, 495-96, 20 USPQ2d 1438, 1444-45 (Fed. Cir. 1991). Our appellate reviewing court set forth numerous factors which are to be considered in determining whether a disclosure would require undue experimentation in ***In re Wands***, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). These factors "include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." ***Id***. In the event of future prosecution,
the examiner should consider whether the specification provides an enabling disclosure of the claimed invention in view of these factors.

As to the case before us, it is recognized that there may be simple assays available by which those skilled in the art would have been able to determine the amount of amino acid

excreted by a particular bacterium, but the examiner should consider whether that information would have enabled such persons to "make" auxotrophic mutants capable of excreting a particular amount of a given amino acid without undue experimentation. The examiner should consider whether the availability of an assay would render the results of any of the chemical mutagenic procedures, spontaneous mutations, etc., described in the specification and the brief, predictable. Is the technique of mutagenizing bacteria with ethyl methane sulfonate (EMS) or N-methyl-N-nitro-N'-nitrosoguanine (NTG), a controlled procedure wherein one can direct the production of a specific mutation? Or, as the results set forth in the appellants' disclosure appear to indicate, do the mutagenesis techniques described in the specification result in random and unpredictable mutations which give rise to numerous, different types of mutants, wherein such mutants may or may not include the types of auxotrophic mutants set forth in the claim? Should the enablement issue arise in future prosecution, the examiner should consider the finding of the court in ***In re Marzocchi***, 439 F.2d 220, 223-24, 169 USPQ 367, 369 (CCPA 1971) that "[i]n

the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim."

Although the appellants' specification describes the construction of two mutants, Gr 7/30-15 #2 and NOA2 8/16-5,[10] which are capable of excreting at least about 5 g/l lysine, the examiner should consider whether the specification provides any teachings or guidelines as to the construction of auxotrophic mutants which are able to secrete at least about 5 g/l of the other amino acids listed in the claim. That is, the examiner should consider whether the construction of two mutants which are capable of excreting at least about 5 g/l lysine would have enabled one skilled in the art to "make" auxotrophic mutants of ***Bacillus*** MGA3 which are capable of excreting 5 g/l of aspartic acid, etc. Does the specification give adequate guidance which would lead such persons toward success in making all of the auxotrophic mutants encompassed

[10] Specification, Table II, p. 32.

by the claims in a predictable manner? Or are the appellants merely offering an "invitation to experiment" to those skilled in the art to perform various mutagenesis techniques and to determine for themselves whether they have obtained an auxotrophic mutant having the claimed characteristics? ***See Genentech, Inc. v. Novo Nordisk A/S***.,
108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997) ("Tossing out the mere germ of an idea does not constitute an enabling disclosure"). Also, ***In re Scarbrough***, 500 F.2d 560, 566, 182 USPQ 298, 302 (CCPA 1974)("It is not enough that a person skilled in the art, by carrying on investigations along the line indicated in the instant application, and by a great amount of work eventually might find out how to make and use the instant invention. The statute requires the application itself to inform, not to direct others to find out for themselves.
In re Gardner et al., 57 CCPA 1207, 427 F.2d 786, 166 USPQ 138 (1970)").

II.

As to the deposit requirement set forth by the examiner,

the appellants are advised that, when an invention involves a biological material, and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner; a deposit of the material may be necessary in order to satisfy the requirements of 35 U.S.C. § 112, first paragraph. An applicant can avoid making a deposit, by demonstrating public accessibility of a biological material; i.e., by establishing that it is "known and readily available." See MPEP § 2404.01 for a description of "known and readily available." It appears from the record that the appellants have deposited the parent ***Bacillus*** MGA3; one type of stable morphological mutant, GR 7/30-15, which is also an auxotrophic mutant capable of excreting at least 5 g/l lysine; and one environmental isolate, NOA2 8/16-5, which appears to be identical to ***Bacillus*** MGA3. The appellants have not deposited any auxotrophic mutants of ***Bacillus*** MGA3 which are capable of excreting at least about 5 g/l aspartic acid, 5 g/l phenylalanine, or 5 g/l tryptophan. Nor have the appellants demonstrated that auxotrophic mutants possessing these properties (i) can be obtained in a reproducible manner, and

(ii) are "known and readily available" to the public. Thus, in the event of further prosecution of the claimed subject matter, the appellants should consider whether they have fully complied with all the requirements of 35 U.S.C. § 112, first paragraph.

III.

According to the appellants, "at the time of the invention, ribulose monophosphate pathway utilizing ***Bacillus*** methylotrophic strains were ubiquitous and widespread in nature." Brief, p. 7. The appellants rely on the teachings of Dijkhuizen (1988), to support their position. ***Id***. In turning to the Dijkhuizen publication, we find that it, in turn, refers to earlier reports of methylotrophic ***Bacillus***, isolated from nature. Dijkhuizen,
p. 209, col. 2.

In the event of future prosecution of the claimed subject matter, the examiner should determine whether all the relevant prior art has been searched and considered. In so doing, the examiner should consider whether the claimed environmental

isolates and morphological mutants of methylotrophic ***Bacillus*** MGA3 are identical, or substantially identical to the methylotrophic ***Bacillus*** described in the prior art. In making such a determination, the examiner should bear in mind the holding of the court in ***In re Best***, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977) that "[w]here, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product."

In addition to affirming the examiner's rejection of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)).

37 CFR § 1.196(b) provides, "A new ground of rejection shall not be considered final for purposes of judicial review."

Regarding any affirmed rejection, 37 CFR § 1.197(b)

provides:

> (b) Appellants may file a single request for rehearing within two months from the date of the original decision . . . .

37 CFR § 1.196(b) also provides that the appellants, ***WITHIN TWO MONTHS FROM THE DATE OF THE DECISION***, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

Should the appellants elect to prosecute further before the Primary Examiner pursuant to 37 CFR § 1.196(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to

the limited prosecution, the affirmed rejection is overcome.

If the appellants elect prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of
Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for reconsideration thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED
37 CFR § 1.196(b)

MARC L. CAROFF Administrative Patent Judge	)
	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
JOAN ELLIS Administrative Patent Judge	)

GRON, Administrative Patent Judge, concurring in-part with the decision of the majority.

Introduction

Claim 55 stands provisionally rejected (1) under 35 U.S.C. § 101 for double patenting of Claims 51 and 52 of Application 08/030,828, filed March 12, 1993, and (2) for obviousness-type double patenting of Claims 25-36 and 51-54 of the same application. The official records of the U.S. Patent & Trademark Office indicate that Application 08/030,828, filed March 12, 1993, has been abandoned. Therefore, the appealed provisional rejections for double patenting and obviousness-type double patent of claims in any patent issuing from Application 08/030828 are moot.[11]

[11] Normally, I would not hesitate to affirm provisional double patenting or obviousness-type double patenting rejections for which appellants indicate, without arguing the merits of the rejections, that they "will file an appropriate terminal disclaimer, if necessary, upon allowance of the claims in either case" (Appellants' Reply Brief, p. 8, final para.) or "will take appropriate action to obviate . . . when and if necessary" (Appellants' Supplemental Reply, p. 2, final para.).

Claim 55 stands rejected under 35 U.S.C. § 112, first and second paragraphs. I would affirm the rejection of Claim 55 under the second paragraph of section 112 in-part for reasons stated by the examiner and in-part for reasons which appear to have escaped the attention of both the examiner and appellants. Accordingly, while I affirm the rejection of Claim 55 under
35 U.S.C. § 112, second paragraph, I also would have designated the affirmance as a new ground of rejection under 37 CFR
§ 1.196(b). Because I affirm the rejection under 35 U.S.C. § 112, second paragraph, we would vacate the examiner's rejections under 35 U.S.C. § 112, first paragraph. It is improper to analyze the claimed subject matter and consider the merits of the rejections under the first paragraph of section 112 "relying on what at best are speculative assumptions as to the meaning of the claims." In re Steele, 305 F.2d 859, 862,
134 USPQ 292, 295 (CCPA 1962). Before considering rejections under 35 U.S.C. § 112, first paragraph, one "must first decide . . . [what] the claims include within their scope." In re

Geerdes, 491 F.2d 1260, 1262, 180 USPQ 789, 791 (CCPA 1974). Before the examiner can analyze claims under 35 U.S.C. § 112, first paragraph, and I can review that analysis, the subject matter the claims encompass must be determined.

> Once having determined that the subject matter defined by the claims is particular and definite, the analysis then turns to the first paragraph of section 112 to determine whether the scope of protection sought is supported and justified by the specification disclosure.

In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). Having determined that appellants' claims do not particularly point out and distinctly claim the subject matter which applicants regard as their invention, as is required by the second paragraph of section 112, I conclude that the examiner cannot have adequately analyzed the full scope of the claimed subject matter and, therefore, the merits of the examiner's rejections under 35 U.S.C. § 112, first paragraph, cannot be properly reviewed.[12]

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[12] Note that a specification need only describe a single method of making the products claimed to enable one skilled in the art to make the full scope of the products claimed if it would have been within the ordinary skill in the art to make the full scope of the products claimed by the single method described without undue experimentation. In re

(continued...)

Claim 55 on appeal reads:

> 55. An amino acid producing auxotrophic bacterium of a biologically pure strain ribulose monophosphate pathway-utilizing bacterium Bacillus MGA3, or biologically pure strain corresponding environmental isolate of Bacillus MGA3 having all of the identifying characteristics of Bacillus MGA3 or biologically pure strain stable morphological mutants of said Bacillus MGA3 or its corresponding environmental isolate, said auxotroph exhibiting sustained

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[12](...continued)
Vaeck, 947 F.2d 488, 495-96, 20 USPQ2d 1438, 1444-45 (Fed. Cir. 1991). See also Engel Indust. Inc. v. Lockformer Co., 946 F.2d 1528, 1533, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991)("The enablement requirement is met if the description enables any mode of making and using the claimed invention.")

> growth at 50°C in nutrient media comprising methanol as a source of carbon and energy and vitamin B_{12} and excreting at least about 5 g/l of lysine, aspartic acid, phenylalanine, or tryptophan when grown on a media containing a nitrogen source.

Discussion

The examiner has intermingled her arguments with respect to the requirements of the 35 U.S.C. § 112, first and second paragraphs. Appellants have similarly responded. Consequently, the issues to be considered to determine compliance with the requirements of each paragraph and the factual findings pertinent to each issue are out of focus. I shall try to delineate the issues and apply the facts as they relate to the requirements of either the first or the second paragraph of 35 U.S.C. § 112.

Under the second paragraph of section 112, the claim must particularly point out and distinctly claim the subject matter applicants regard as their invention. The examiner argues that certain terms utilized to define "[a]n amino acid producing auxotrophic bacterium of a biologically pure strain ribulose monophosphate pathway-utilizing bacterium Bacillus MGA3, or biologically pure strain corresponding environmental

isolate of Bacillus MGA3 having all of the identifying characteristics of Bacillus MGA3 or biologically pure strain stable morphological mutants of said Bacillus MGA3 or its corresponding environmental isolate" render the claimed subject matter so vague and indefinite that persons skilled in the art could not have reasonably understood or determined which auxotrophic bacteria are and which are not encompassed by appellants' Claim 55. Appellants retort that the language read as a whole in light of the teaching in the specification reasonably would have apprised persons skilled in the art of the metes and bounds of the claimed auxotrophic bacteria. However, the examiner's and appellants' arguments so invade the province of the written description, enablement, and best mode requirements of the first paragraph of section 112 that their vision of the subject matter claimed has been obscured. As a result, neither the examiner nor appellants have adequately considered the full scope of the claimed subject matter in light of the function limitations in the claim and the description of appellants' invention in the specification.

I hold that persons having ordinary skill in the art would not have been confused by the language which appellants

used to define the claimed auxotrophic bacteria if (1) the claimed auxotrophic bacterium is adequately defined by its properties, and (2) persons skilled in the art would have known or learned from appellants' specification how to screen auxotrophic Bacillus MGA3, or biologically pure strain corresponding environmental isolate of Bacillus MGA3 having all of the identifying characteristics of Bacillus MGA3 or biologically pure strain stable morphological mutants of said Bacillus MGA3 or its corresponding environmental isolate, for their defining properties.[13] Certainly, the question to be asked under the second paragraph of section 112 is not whether the specification would have enabled one skilled in the art to make and use auxotrophic bacteria which function in the manner indicated in the claim. The question to be asked is whether

[13] Having read the majority opinion, I must add that persons having ordinary skill in the art would not have been confused by the language which appellants used to define the claimed auxotrophic bacteria if, as a matter of law, Claim 55 reasonably would have been interpreted in light of the specification as directed exclusively to auxotrophic bacteria, an interpretation which is, in my view, reasonably consistent with the specification's description of the invention. See the Summary of the Invention (Spec., pp. 2-5). However, I will concede that the majority's interpretation of the scope of the subject matter claimed is not spurious.

the auxotrophic bacteria encompassed by appellants' claim can readily be identified. The second paragraph of section 112 does not require that the specification enable one skilled in the art to make and use the full scope of auxotrophic bacteria encompassed by the claims. It only requires that the skilled artisan be able to distinguish the auxotrophic bacteria which is claimed from auxotrophic bacterium which is not encompassed by the claim without undue experimentation.

To determine whether or not the requirements of the second paragraph of section 112 have been satisfied, we need not concern ourselves with bacteria deposits or the amount of experimentation one skilled in the art would have been required to perform to make and use the full scope of the claimed invention. If persons skilled in the art could have readily identified the auxotrophic bacteria encompassed by appellants' claims in light of the teaching in the specification, the requirements of 35 U.S.C. § 112, second paragraph, are satisfied.

Even assuming the Claim 55 is not drawn exclusively to auxotrophic bacteria, I conclude that the specification supporting Claim 55 on appeal would have clouded rather than

clarified the skilled artisan's recognition, understanding, and/or identification of the auxotrophic bacteria encompassed by the claims. The claimed auxotrophs are not simply auxotrophs of deposited bacterium MGA3, auxotrophs of biologically pure strain corresponding environmental isolate of bacterium MGA3 having the identifying characteristics of bacterium MGA3 that are listed in Table 1 on page 8 of the specification, or auxotrophs of biologically pure strain stable morphological mutants of said bacterium MGA3 or its corresponding environmental isolate, they are auxotrophic bacteria which (Claim 55):

(a) exhibit "sustained growth at 50^{o}C in nutrient media comprising methanol as a source of carbon and energy and vitamin B_{12}," and

(b) excrete "at least about 5 g/l of lysine, aspartic acid, phenylalanine, or tryptophan when grown on a media containing a nitrogen source."

While I agree with the majority that appellants' specification does not "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as the invention" as the

second paragraph of section 112 requires,[14] it is not clear to me that the claims are limited to the inventions described in the specification. For example, the specification states:

> This invention relates to production of amino acids using auxotrophic mutants of a methylotrophic Bacillus [(Spec., p. 1, lines 13-14)].
>
> We have discovered a biologically pure strain of a type I methylotrophic bacterium of the genus Bacillus which exhibits sustained growth at 50°C in nutrient media comprising methanol as a source of carbon and energy, vitamin B_{12} and biotin [(Spec., p. 2, line 30, to p. 3, line 2)].
>
> . . .
>
> In a preferred embodiment, an amino acid auxotroph of the biologically pure strain type I methylo-trophic bacteria of the genus Bacillus produces at least one amino acid when cultured at 50°C in an aqueous nutrient media having a carbon and energy source, preferably methanol, a nitrogen source, vitamin B_{12} and biotin [(Spec., p. 3, lines 7-13)].
>
> . . .
>
> We have observed that using the method of the

[14] It should be apparent from the majority and my opinion that, while our interpretations of the scope of the claimed subject matter differ significantly, Claim 55 clearly does not particularly point out and distinctly claim the subject matter applicants regard as their invention.

present invention, auxotrophic bacteria of a biologically pure strain of type I methylotrophic Bacillus excrete substantial amounts of lysine. In a preferred embodiment we have observed an amino acid auxotroph excreting from about 3 - 10 grams/per liter L-lysine [(Spec., p. 4, lines 12-17)].

. . .

Primary characteristics of the bacterium of the present invention are that it grows at a temperature of at least 50^{0}C in an aqueous nutrient media that includes methanol as a sole carbon and energy source with biotin, and vitamin B_{12} s a required vitamins [sic][(Spec., p. 9, lines 23-27)].

. . .

Growth requires biotin in amounts from about 20 $ug \cdot 1^{-1}$ to 20 $mg \cdot 1^{-1}$. When grown in minimal salts media with methanol,

vitamin B_{12} and biotin the bacterium of the present invention can grow at a rate from about 0.2 hr^{-1} to about 1.5 hr^{-1}. at a temperature of about 50EC to 60EC [(Spec., p. 10, lines 27-31)].

. . .

It is envisioned that the present invention can be employed to produce amino acid auxotroph and/or amino acid analog resistant mutants of the type I methylotrophic bacterium of the genus Bacillus described herein that are capable of producing most, if not all, of the known amino acids. [(Spec. p. 13, lines 5-10)].

To produce amino acids from auxotrophic and/or amino acid resistant mutants of the type I methylotrophic Bacillus of the present invention, the organism is cultured in an aqueous nutrient medium having biotin, vitamin B_{12}, and methanol together with amounts of a phosphate source, a sulfate source, a nitrogen source, calcium and trace elements in amounts such as indicated in Example 4. [(Spec. p. 13, lines 11-17)].

. . .

At a minimum, at least about 0.05% wt/vol. methanol, 0.5 $ug \cdot 1^{-1}$ vitamin B_{12} and about 20 $ug \cdot 1^{-1}$ to about 20 $mg \cdot 1^{-1}$ biotin are needed for mutant production of amino acids [(Spec., p. 13, lines 25-28)].

. . .

Employing auxotrophs and/or amino acid resistant mutants of the type I methylotrophic bacterium of the present invention it is believed that amino acids can be produced in substantial quantities. That is, quantities of amino acids from at least 5 $grams \cdot 1^{-1}$ . . . can be produced. While the present invention is believed useful to produce many of the 20 amino acids, it is especially

> useful to produce lysine, phenylalanine, and tryptophan either singly or simultaneously. In one embodiment, auxotrophs which are also amino acid sensitive can produce from about 3 to about 5 grams$\cdot 1^{-1}$ of lysine. In a preferred embodiment, auxotrophs which are also amino acid sensitive can produce up to 8 grams/l L-lysine. Simultaneous production of at least 4.0g$\cdot 1^{-1}$ of L-lysine and at least 1.5g$\cdot 1^{-1}$ of L-aspartic acid can also be obtained. In one preferred embodiment, simultaneous production of 4.5g$\cdot 1^{-1}$ of L-lysine and 2.0g$\cdot 1^{-1}$ of L-aspartic acid are obtained [(Spec., p. 14, line 15, to p. 15, line 1)].

The auxotrophic bacterium of Claim 55 must exhibit "sustained growth at 50^{E}C in nutrient media comprising methanol as a source of carbon and energy and vitamin B_{12}" (emphasis added) and excrete "at least about 5 g/l of lysine, aspartic acid, phenylalanine, or tryptophan when grown on a media containing a nitrogen source" (emphasis added). However:

(1) The specification teaches that appellants' novel amino acid producing auxotrophic bacterium requires biotin to grow (Spec., p. 10, line 27). Claim 55 appears also to be directed to amino acid producing auxotrophic bacteria which exhibit sustained growth in a nutrient media which does not contain biotin.

(2) The specification teaches that appellants' novel amino acid producing auxotrophic bacterium grows at a temperature of at least 50^{0}C "in an aqueous nutrient media that includes methanol as a sole carbon and energy source with biotin, and vitamin B_{12}" (Spec., p. 9, lines 24-26). Claim 55 appears also to be directed to amino acid producing auxotrophic bacteria which exhibit sustained growth in a nutrient media "comprising methanol," i.e., in a nutrient media that includes "carbon and energy sources for growth other than methanol; including glucose or mannitol" (Spec., p. 10, lines 5-6).

(3) The specification appears to teach that appellants' novel amino acid producing auxotrophic bacteria are especially useful to produce lysine, phenylalanine, and tryptophan singly or simultaneously in quantities from at least 5 grams$\cdot 1^{-1}$ (Spec., p. 14, lines 15-25) in nutrient media comprising methanol as a sole carbon and energy source with biotin, and vitamin B_{12}. Claim 55 appears to encompass amino acid producing auxotrophic bacteria which produce at least about 5 g/l of lysine or any amount of aspartic acid, phenylalanine or tryptophan, or at

least about 5 g/l of lysine, 5 g/l of aspartic acid, 5 g/l of phenylalanine or 5 g/l of tryptophan when grown on "a media" containing a nitrogen source. It is not clear from the specification that the functional limitations on production of the specified amino acids apply where the bacteria grows in media comprising methanol as a sole carbon and energy source with biotin, and vitamin B_{12}, in media comprising methanol as a carbon and energy source with biotin, and vitamin B_{12}, or in any other media. Moreover, the claim is itself unclear and the specification does not help clarify what minimum quantity of lysine, aspartic acid, phenylalanine "or" tryptophan production in what kind of media satisfies the functional limitations in the claim.

Because the functional criteria by which the claimed amino acid producing auxotrophic bacteria are defined are inconsistent with the description of the properties of the novel auxotrophic bacteria described in the specification, it is my view that persons skilled in the art reasonably would not have understood and could not have readily identified the amino acid producing auxotrophic bacteria encompassed by Claim 55. This holding is sound whether or not appropriate screen

tests to determine whether newly produced auxotrophic bacteria satisfy one or all the functional limitations encompassed by the claim language were available. One skilled in the art cannot screen auxotrophic bacteria for functional limitations which are not clearly and distinctly stated in the claims, especially when the specification suggests that the properties which characterize
the inventive auxotrophic bacteria are substantially different. Here, the functional limitations Claim 55 places on appellants' novel auxotrophic bacteria are so vague and indefinite that appellants appear improperly to be claiming subject matter which they do not regard as their invention. Therefore, I conclude that Claim 55 is unpatentable under 35 U.S.C. § 112, second paragraph. Because the reasons for my conclusion differ substantially from those provided by the examiner, I also would denominate my affirmance of the appealed rejection under
35 U.S.C. § 112, second paragraph, a NEW GROUND OF REJECTION under 37 CFR § 1.196(b).

Because I hold that the metes and bounds of the claimed subject matter is unclear, I cannot properly and do not reach

the merits of the examiner's rejections under 35 U.S.C. § 112, first paragraph. Moreover, because it is improper to determine whether appellants' specification would have enabled persons skilled in the art to make and use the full scope of the invention claimed without reasonably understanding or being able to ascertain the full scope of the subject matter claimed, I vote to VACATE the examiner's rejections of Claim 55 under 35 U.S.C. § 112, first paragraph, and recommend that they not be reentered until such time as Claim 55 satisfies the requirements of 35 U.S.C. § 112, second paragraph.

Conclusion

I agree with the majority that the rejection of Claim 55 under 35 U.S.C. § 112, second paragraph, should be affirmed. Because the reasons why I would affirm the rejection differ substantially from those provided by the examiner, I also would denominate my affirmance a NEW GROUND OF REJECTION under 37 CFR

§ 1.196(b).

However, I would vacate and remand rather than decide the merits the examiner's rejections of Claim 55 under 35 U.S.C. § 112, first paragraph.

The examiner's provisional rejections of Claim 55 under 35 U.S.C. § 101 for double patenting of Claims 51 and 52 of abandoned Application 08/030,828, filed March 12, 1993, and for obviousness-type double patenting of Claims 25-36 and 51-54 of the same abandoned application are moot.

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	)	

Alan W. Kowalchyk
Merchant, Gould, Smith,
Edell, Welter & Schmidt
3100 Norwest Center
90 South Seventh Street
Minneapolis, MN 55402